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Invited Commentary

Neurogenic bowel and bladder evaluation strategies in spinal cord injury: New directions

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Depending upon level and completeness of injury, spinal cord injury (SCI) is associated with a range of comorbidities that can limit functional independence, mobility and socialization. These conditions include, but are not limited to motor paralysis, sensory loss, neurogenic lung disease (restrictive and obstructive), neurogenic bradycardia, neurogenic hypotension, sympathetic blunting, autonomic dysreflexia, neurogenic adaptive myocardial atrophy, anabolic deficiency, spasticity, sarcopenia, heterotopic ossification, osteoporosis, upper extremity overuse, neurogenic obesity, metabolic syndrome (including dyslipidemia, hypertension, type 2 diabetes mellitus and coronary artery disease), pressure injuries, sexual dysfunction, and neurogenic bowel and neurogenic bladder. Among these, the last two have consistently been identified as the most disruptive to perceived independence, self-efficacy, and quality of life.[1–4]

Toward fulfilling its vision to empower persons with SCI to lead "full and productive lives as active participants in their communities," in March 2017, the Craig H. Neilsen Foundation coordinated a workshop of experts and consumers in the field to address the translation of bowel and bladder management research through the continuum of preclinical, clinical and community implementation. Priorities established during that workshop included the need to (1) update clinical standards for clinicians and consumers, (2) understand bowel physiology and establish targets for therapeutic intervention, (3) identify sensory technology to alert individuals to bowel and bladder fullness and the need to void, (4) optimize neuromodulation to replace or restore gastrointestinal and genitourinary functional control, and (5) methodically quantify the influence of diet and activity on gastrointestinal and genitourinary function.[5] An overarching priority emerged to identify metric standards that could be used across the preclinical and clinical research continuum to optimize translational research applications.

To that end, this issue of the Journal of Spinal Cord Medicine features two articles addressing bowel and bladder evaluation strategies that can be utilized across the preclinical and clinical research continuum. In "Recommendations for evaluation of bladder and bowel function in preclinical spinal cord injury research," Holmes *et al.* identify and distinguish outcome metrics as fundamental, recommended, supplemental, exploratory, or not recommended.[6] Fundamental measures for bowel and bladder assessments were further distinguished by tissue morphology, voiding efficiency, and smooth muscle-mediated pressure studies, all of which could be translated to clinical outcome metrics currently employed or to be developed.[6]

For the lower urinary tract (LUT) and bowel, a rigorous process was used to identify functional, histological, biochemical, physiological, electrophysiological, and imaging techniques for consideration of ease of use, affordability, time/effort requirements, reliability, and prior demonstration of sensitivity to change with an intervention. While bladder outcome metrics in preclinical trials appear to have been better studied and understood, only three were ultimately listed as being foundational: tissue morphology, voiding dynamics, and cystometry with or without external sphincter electromyography; additionally, metabolic cages were recommended to quantify fluid intake and output.

In addition to somatic, sympathetic, and parasympathetic innervation shared with the genitourinary system, the gastrointestinal system is further complicated by an enteric (intrinsic) nervous system that can function independently from the aforementioned neural influences. Although less understood, bowel function

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assessment tools also include three foundational elements, including tissue morphology, metabolic cages, and pressure recordings of both proximal and distal gut. Five additional outcome metrics for bowel assessment were recommended for preclinical investigators, including immunochemistry of the enteric nervous system, fecal analysis, whole gut transit studies, motility studies of the distal colon, and muscle tension recordings of colonic smooth muscle. The authors concluded that these standardized metrics should be adopted for all preclinical interventional gastrointestinal and genitourinary studies in animals with SCI, with a few additional investigator-selected study-relevant supplemental measures.[6]

The companion article in this issue, "Recommendations for evaluation of neurogenic bladder and bowel dysfunction after spinal cord injury and/or disease," continues a similar rigorous assessment of clinical tools and metrics advocated for use in clinical trials.[7] Tate *et al*. provides recommendations for use of 15 clinical assessments for evaluating neurogenic bladder dysfunction in persons with SCI, including voiding diaries, physical examination findings, urinalysis, urine microscopy, urine culture and sensitivity, glomerular filtration rate, renal/bladder ultrasound, abdominal radiographs, abdominal computed tomography (CT) scan, renal scintigraphy, intravenous pyelography, uroflowmetry, post-void residual volume, urodynamics, and cystourethroscopy. Several of these metrics mirrored those recommended by the preclinical evaluation team.

Similarly, 12 objective assessments of bowel function were identified and recommended for the clinical assessment of persons with SCI or dysfunction (SCI/D), including bowel diaries, physical examination findings, stool sample analysis, abdominal radiographs, abdominal CT scan, endoscopy/colonoscopy, gastric-emptying studies, total and segmental colonic transit time, wireless motility capsule for bowel transit, anorectal manometry with or without balloon expulsion, pudendal nerve conduction with pelvic floor EMG, and defecography. As for the preclinical tools, recommendations for these clinical assessment tools were based on specific medical needs of the patient.[7]

Additionally, in accord with consumer concerns, Tate *et al.* identified eight self-report measures for bladder and bowel dysfunction following a two-phase rigorous evaluation for final review. Three of these instruments, including the Qualiveen 30,[8] Short-Form (SF) Qualiveen,[9] and Neurogenic Bowel Dysfunction Score (NBDS)[10] have been recommended as supplemental, highly recommended measures for inclusion in clinical trials of bowel and bladder function due to their strong psychometric abilities and extensive use in SCI populations. Because these instruments utilize ordinal data, investigators are cautioned to restrict analyses to non-parametric statistical tools. Finally, this article identified elements of the International SCI Bowel Function Basic Data Set (ISCIBF BDS)[11] and International Lower Urinary Tract Function Basic Data Set (LUTF BDS)[12] that could be recommended as supplemental.

Both articles represent robust and essential recommendations from experts in their respective fields of preclinical and clinical spinal cord research that are endorsed by consumers of SCI/D care. Preclinical and clinical researchers in neurogenic bladder and bowel should take heed of these recommendations as they consider methodology for their respective studies and trials, recognizing the importance of clinical translation as well as expert and consumer consensus for outcome metrics.

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